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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Received
SEP 15 2006

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 4,965,204 was filed on August 31, 1999, under 35 U.S.C. § 156 based upon the regulatory review of the product ISOLEX 300 (or ISOLEX 300i). Applications for patent term extension for U.S. Patent Nos. 4,714,680, 5,035,994, and 5,130,144 have also been filed, requesting extension based upon regulatory review of ISOLEX 300 (or ISOLEX 300i). Applicant recognizes that only a single patent can be extended, and requests that review of the applications other than for U.S. Patent No. 4,714,680 be held in abeyance. Since 35 U.S.C. § 156(d)(2)(A) requires the Commissioner to notify the Secretary of Health and Human Services if the patent claims a product subject to review by the Federal Food, Drug and Cosmetic Act (FFDCA), or the method of use or manufacturing such a product, within 60 days of the submittal of an application for patent term extension, no application can be held in abeyance.

The assistance of your Office is requested in confirming that the product identified in the application, ISOLEX 300 AND ISOLEX 300i, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product, or the method of use of manufacturing such a product, which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A certificate of correction, not a reexamination certificate, is attached at Exhibit D.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson

Karin Tyson, Senior Legal Advisor, Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: James W. Inskeep
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